IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs, v. JOHNSON & JOHNSON, INC. and CORDIS CORPORATION, Defendants.	Civil Action No. 07-333-SLR Civil Action No. 07-348-SLR Civil Action No. 07-409-SLR
BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs, v. JOHNSON & JOHNSON, INC., CORDIS CORPORATION, and WYETH Defendants.	Civil Action No. 07-765-SLR **REDACTED – PUBLIC VERSION**

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Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively "BSC") submit this responsive Markman brief in support of their proposed claim constructions with respect to United States Patent Nos. 7,217,286 ("the '7286 Patent"), 7,223,286 ("the '3286 Patent"), 7,229,473 ("the '473 Patent") (collectively "the 1997 Patents"), and 7,300,662 (the '662 Patent").[1] Not every disputed claim limitation is discussed in this brief, and BSC continues to rely on the arguments set forth in its September 16, 2009 Opening Markman Brief ("BSC Opening Brief") (D.I. 254)[2].

INTRODUCTION

Cordis's assertion that it has grounded its claim constructions in the intrinsic evidence is belied by the vast amount of extrinsic evidence it cites to support (or to create out of whole cloth) virtually every claim construction it offers. Cordis replaces the actual language of the patent – such as an explicit definition in the patents' specification of the claim term "biocompatible" – with a variety of explanations from Cordis's advocates/experts as to what allegedly would have been understood by one of ordinary skill. If there is language missing from the claims that Cordis wishes were there – such as functional or structural limitations on rapamycin analogs – its experts simply opine that one of ordinary skill would know that the inventors really meant for the missing language to be a part of the invention. In sharp contrast to BSC, which has drawn its

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[1] Citations to "Ex." refer to exhibits to either (1) the Joint Appendix of Exhibits to the Parties' *Markman* Briefs which is submitted herewith, (2) Plaintiffs' Appendix of Exhibits to Their *Markman* Brief, which was previously filed as D.I. 255, and (3) Plaintiffs' Supplemental Appendix of Exhibits to Their *Markman* Brief which is also submitted herewith and contains Exhibits T-V. Citations to Joint Appendix are denoted by the pin-cites "JA-__," while citations to the Plaintiffs' appendices are denoted by the pin-cites "BSC-A-__."

[2] Unless otherwise indicated, the D.I. numbers in this brief refer to documents filed in connection with C.A. No. 07-333-SLR.

proposed claim constructions directly from the claims and the specifications of the patents-in-suit, Cordis and its experts have, under the guise of claim construction, rewritten the claims.

Even worse, Cordis's experts provide opinions (often not contained in their previous expert reports) that contradict what they have said before. For example, in an attempt to salvage the claims of the patents-in-suit at issue in this case – every one of which stands rejected as obvious at the Patent Office as a result of ongoing reexamination proceedings – Cordis has submitted expert declarations asserting that the stent claimed in those patents prevents neointimal proliferation to achieve "zero restenosis" and "solve the problem of restenosis." Yet, in order to preserve Cordis's claim of infringement by BSC's PROMUS stent, the very same experts declare to this Court that the claimed stents need not actually prevent neointimal proliferation at all; they simply need to reduce it by a small amount. Similarly, Cordis relies on a prior art patent that discloses multiple layer coatings to support its construction of the claims asserted here; before the Patent Office, however, Cordis's own expert specifically relied on the same prior art patent's multi-layer coating to distinguish that patent from the patents-in-suit.

As recognized in *Phillips v. AWH Corp.*, "undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents." 415 F.3d 1303, 1319 (Fed. Cir. 2005) (quoting *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995)). The Opening Markman Brief of Johnson & Johnson, Cordis Corporation, and Wyeth (D.I. 266) ("Cordis Brief") serves as an object lesson in the dangers of admitting such evidence, including the expert declarations signed by Dr. Mikos and Cordis's other experts, to alter the plain language of claims. Again, not only do Cordis's experts present claim constructions that ignore

and contradict the intrinsic record, but these constructions have shifted and changed numerous times over the course of expert discovery. Dr. Mikos in particular has repeatedly shifted and changed his opinions, filing a supplemental report after the expert report deadline which precipitated BSC's currently pending motion to strike (*see* D.I. 251) and adding several more new opinions in the declaration submitted in connection with Cordis's claim construction briefing. These repeated shifts in position beg the question of whether Dr. Mikos will consider the claims of the patents-in-suit to mean something different tomorrow than they do today. The meaning of patent claims, however, simply does not change at the whim of an expert offering opinions years after those claims emerged from the Patent Office. Cordis's experts' inability to present consistent constructions highlights the frivolity and unreliability of those constructions and supports BSC's claim construction approach, which focuses exclusively on and is strongly supported by the intrinsic record.

ARGUMENT

I. CLAIM TERMS FROM THE 1997 PATENTS

A. Rapamycin And Its Analogs

1. "Rapamycin"

Cordis concedes that BSC has properly identified the chemical structure of rapamycin in its proposed definition. Cordis's only concern – that a drawing of a chemical structure cannot be read aloud to a jury – is irrelevant, given that copies of the jury instructions are provided to the jury. During trial, both parties will no doubt present the jury with representations of the structures of both rapamycin and other, possibly related compounds, pointing out their differences or similarities. Having a diagram of the actual chemical structure of rapamycin in the jury room will be helpful to the jury when discussing these chemical compounds, either in the

accused products or in the prior art. Cordis's proposal, which simply recites another name for rapamycin, fails to actually identify or clarify the claimed chemical structure.

2. "Macrocyclic Lactone Analog"

Cordis's definition of "macrocyclic lactone analog" departs from the ordinary meaning of the phrase by requiring that the analog have: (1) particular functional limitations and (2) the ***identical*** macrocyclic lactone ring as rapamycin.

a. The 1997 Patents Do Not Require That "Macrocyclic Lactone Analogs" Possess Any Particular Functionality

Cordis appears to concede that the ordinary meaning of a chemical "analog" conveys only structural similarity, without any particular functionality. Indeed, this proposition is hard to dispute, given the various dictionary definitions previously cited by BSC (and Cordis). (BSC Opening Brief at 8-11). Cordis's contention that a functional limitation is necessary – *i.e.*, that the analog must be "capable of inhibiting both the inflammatory response known to occur after arterial injury and stent implantation, as well as the SMC [smooth muscle cell] hyperproliferative response" – because "[t]he specification makes clear that the claimed analogs must do similar things as sirolimus" (Cordis Brief at 25) is wrong for several reasons.

As an initial matter, Cordis fails to acknowledge that the ***claims themselves*** expressly recite the "thing" that rapamycin and its claimed analogs must do – "inhibit neointimal proliferation." (Ex. 1, '7286 Patent at claim 1 (JA-18); Ex. 3, '473 Patent at claim 1 (JA-57); Ex. 2, '3286 Patent at claims 32 and 40 (JA-38-39).) Importing Cordis's implicit functional limitations into the definition of "analog" would impermissibly render superfluous portions of the claims that explicitly recite the functionality of the drug. *See Mangosoft, Inc. v. Oracle Corp.,* 525 F.3d 1327, 1330-31 (Fed. Cir. 2008) (rejecting a claim construction that renders claim

language superfluous); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1325 (Fed. Cir. 2001) (same).

Further, Cordis's reading of the specification and what it supposedly "makes clear" about analogs is incorrect. The 1997 Patents contain only two passing references to analogs of rapamycin, with no substantive discussion whatsoever. (BSC Opening Brief at 10-11; *see also* BSC's Opening Brief in Support of its Motion for Summary Judgment of Invalidity of U.S. Patent Nos. 7,217,286, 7,223,286, 7,229,473, and 7,300,662 Under 35 U.S.C. § 112 (D.I. 257) at 6-8.) Cordis's reliance on portions of the specification that describe various properties of rapamycin that were known in the prior art (Cordis Brief at 25-26) is misplaced. These passages do not purport to redefine "macrocyclic lactone analogs" of rapamycin to include certain functionalities and cannot justify Cordis's attempts to change the ordinary meaning of this term. *Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000) (if the meaning of a particular claim term is asserted as something other than the ordinary meaning, the intrinsic evidence must "clearly redefine" a claim term so as to put one reasonably skilled in the art on notice that the patentee intended to so redefine the claim term); *SunRace Roots Enters. Co. v. SRAM Corp.*, 336 F.3d 1298, 1304 (Fed. Cir. 2003) ("Claim terms take on their ordinary and accustomed meanings unless the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope").

Cordis likewise misreads the prosecution history. To the extent it is relevant at all, the language cited by Cordis strongly suggests that ***structural*** similarity is the hallmark of an analog: "The attached drawings show the chemical structure of both rapamycin and paclitaxel. Upon a

review of the images, one can see clearly that the chemical structures of these compounds share little in common. In this regard, one could not characterize the two families of drugs as 'analogues.'" (Cordis Brief at 26-27 (citing the '480 Application prosecution history)).

Cordis's reliance on a portion of the prosecution history referencing the methods of action of rapamycin (*see id.*) is similarly unavailing for at least two reasons. *First*, this language does not provide any detail about rapamycin's method of action and does not clearly redefine the ordinary meaning of "analog." *AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1381 (Fed. Cir. 2005) (representations made during prosecution must be unambiguous and contain clear disavowals of claim scope; otherwise the prosecution history is not entitled to "much weight"); *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1287 (Fed. Cir. 2005) ("There is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term"). Indeed, because the inventors admit in the patent itself that the mechanism of action of rapamycin was not definitively known, they could not have implicitly defined rapamycin analogs in terms of a particular mechanism of action. (Ex. 1, '7286 Patent at 5:36-38 (JA-17).) *Second*, even if the prosecution history somehow required particular mechanisms of action for rapamycin analogs (which it does not), the Court still would have no basis for adopting Cordis's proposed construction because it does not recite any methods of action of rapamycin. The functional limitations that Cordis seeks to add to the claims – inhibition of inflammation and hyperproliferation – are not mechanisms of action. Indeed, one of the functions Cordis seeks to add – inflammation – is not even mentioned in the prosecution history cited by Cordis. (Cordis Brief at 26-27). And, when the prosecution history discusses a drug (taxol) that does "exhibit antiproliferative properties," Cordis argues that this drug is not an analog despite sharing this

functionality with rapamycin. (*Id.*) Thus, Cordis's cited prosecution history counsels against, not for, Cordis's construction.

The extrinsic declaration of Dr. Sabatini, submitted by Cordis, illustrates the highly arbitrary nature of the functional language Cordis seeks to add to the claims. (*See* 9/16/09 Declaration of David Sabatini, M.D., Ph.D. (D.I. 270) ("Sabatini Dec.").) [redacted] Cordis's importation of arbitrary language from the specification into the claims can only lead to mischief and is not a legitimate part of the claim construction process. *Phillips*, 415 F.3d at 1323 (unjustified importation of limitations from the specification is improper as a matter of law).

b. The 1997 Patents Do Not Require That A Macrocyclic Lactone Analog Have A Macrocyclic Lactone Ring *Identical* To That Of Rapamycin

The claim language, by its plain meaning, requires only that a macrocyclic lactone analog be a macrocyclic lactone and be structurally similar to rapamycin. The general definitions of "macrocyclic" and "lactone" provided both by Cordis and BSC demonstrate that there are innumerable macrocyclic lactones. Further, there is nothing in the definition of "analog" that

requires identity – an analog, by definition is ***not*** identical to another compound and the dissimilarity can occur anywhere on the molecule. (BSC Opening Brief at 9-11.)

Cordis therefore diverges from the ordinary meaning "macrocyclic lactone analog" when it insists that the analog must have a macrocyclic lactone ring identical to that of rapamycin. Cordis cites no intrinsic evidence to support this divergence, which, by itself, is fatal to Cordis's argument. *Phillips*, 415 F.3d at 1318-19; *see Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).[3]

The patents themselves contradict Dr. Sabatini's extrinsic declaration on which Cordis relies. [redacted] The law of claim construction precludes courts from relying on such mouthpiece experts to give claim terms special meanings not set forth anywhere in the patents themselves. *Phillips*, 415 F.3d at 1318 (courts should "discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent'"); *DESA IP, LLC v. EML Techs., LLC*, 211 Fed. Appx. 932, 936-37 (Fed. Cir. 2007) ("Expert testimony in conflict with the intrinsic evidence …

[3] Again, as noted in BSC's Opening Brief, adding a requirement that limits the claims to only those analogs that have a macrocyclic lactone ring structure identical to that of rapamycin would be improper since this would exclude compounds such as tacrolimus, a molecule which has a macrocylic ring that is different from that of rapamycin but is admittedly a "structural analog" of rapamycin. (*See* BSC's Opening Brief at note 14.)

should [be] accorded no weight"); *Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353, 1361 (Fed. Cir. 2005) ("Expert testimony at odds with the intrinsic evidence must be disregarded").[4]

Even if his opinion were legally relevant and not inaccurate, Dr. Sabatini still provides no basis on which the Court could conclude that the 1997 Patents redefined the ordinary meaning of "macrocyclic lactone analog." [redacted] It would not, however, lead to the conclusion that the inventors somehow claimed (without so stating) that a "macrocyclic lactone analog" must have a macrocyclic lactone ring ***identical*** to that of rapamycin. [redacted] Thus, BSC's construction, which sets forth the ordinary meaning of the words "macrocyclic lactone analog," is fully consistent with any belief in the prior art that the macrocyclic lactone ring portion of rapamycin contributed to its anti-proliferative properties.

Moreover, even if Dr. Sabatini has somehow correctly divined the inventors' secret intentions with respect to the meaning of "macrocyclic lactone analog," such subjective intentions do not operate to change the ordinary meaning of claim terms. *Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc.*, 344 F.3d 1186, 1194 (Fed. Cir. 2003) ("what the patentee

[redacted]

subjectively intended his claims to mean is largely irrelevant to the claim's objective meaning and scope").[5]

B. "Biocompatible"

1. The 1997 Patents Explicitly Define "Biocompatible"

While Cordis improperly relies on extrinsic evidence to alter the ordinary meaning of "macrocyclic lactone analog," it takes this error one step further by relying on extrinsic evidence to supplant the explicit definition of "biocompatible" set forth in the patent specification. Because the law clearly holds that the explicit definition in the patent controls, "biocompatible" is perhaps the easiest of the disputed claim terms in the 1997 Patents to construe. *Phillips*, 415 F.3d at 1316.

Although Cordis wants to ignore that the patent provides a definition of "biocompatible," the patent is unequivocal: "Polymers are biocompatible (i.e., not elicit any negative tissue reaction or promote mural thrombosis formation)...." (Ex. 1, '7286 Patent at 6:37-39 (JA-17).) As the Federal Circuit recently confirmed in a medical device case, the use of "i.e." is plainly definitional.[6] *Edwards Lifesciences LLC v. Cook Inc.*, ___ F.3d ___, No. 2009-1006, 2009 U.S. App. LEXIS 20906, at *31-32 (Fed. Cir. Sept. 22, 2009) ("the specification's use of 'i.e.' signals

[redacted]

[6] "I.e." is short for "id est," Latin for "that is." (Black's Law Dictionary 745 (6th ed. 1990).

an intent to define the word to which it refers ..."); *see also Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1327, 1330 (Fed. Cir. 2003).[7]

Cordis's proposed construction of "biocompatible" – "able to perform its function in the body with an acceptable biological response" – is not consistent with the patents. Cordis's construction would allow the polymer to elicit a negative tissue reaction, as long as the negative tissue reaction was "acceptable" (to some unnamed party) and allowed the device to "perform its function in the body." The patents' definition, in contrast, requires that the polymer not elicit ***any*** negative tissue reaction. Only BSC's proposed construction, which repeats the express definition in the patents, is consistent with the intrinsic evidence.

And, Cordis's argument that BSC uses "only a part of what the specification has to say about the meaning of a 'biocompatible' polymer" (Cordis Brief at 17) is demonstrably false. *First*, BSC has relied on the portion of the specification that explicitly defines "biocompatible" and thus controls the claim construction analysis. *Second*, no other portion of the specification modifies or elaborates on that definition of "biocompatible" (implicitly or explicitly). The word "biocompatible" appears only three times in the specification. (Ex. 1, '7286 Patent at 6:37-39, 6:43-45, and 7:24-25 (JA-17-18).) The above-quoted portion of the specification, on which BSC relies, is the first appearance of the word "biocompatible" in the patents. Subsequently, there are two references to biocompatible polymers, but neither of those describes the *in vivo* effects that would make a polymer "biocompatible" and have no bearing on the construction of that term. (*See* Ex. 1, '7286 Patent, 6:37, 44 (JA-17).) Therefore, only BSC's proffered construction is supported by the specification.

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[7] The fact that the specification uses "e.g." multiple times in the same paragraph demonstrates that the inventors understood the difference between "e.g." and "i.e." and intended to define the term biocompatible when it used "i.e." (Ex. 1, '7286 Patent at 6:37, 6:40, 44 (JA-17).)

Similarly frivolous is Cordis's assertion that the prosecution history somehow justifies its failure to follow the patents' definition of "biocompatible." (Cordis Brief at 16.) Cordis reasons that (1) in 2006 (about a decade after the priority date), Cordis's patent attorney sought to accelerate the '3286 Patent's prosecution on the grounds that the PROMUS stent infringed the patents; (2) PROMUS is not "biocompatible" as that term is defined in the patent specification because it elicits a negative tissue response; therefore (3) the definition of "biocompatible" in the patents, which excludes PROMUS, cannot be adopted. The fact that PROMUS ***admittedly*** is not "biocompatible" as that term is defined in the 1997 Patents, however, does not provide support for changing the definition, to the contrary, it provides support for BSC's pending motion for summary judgment of non-infringement. (*See* Plaintiffs' Motion for Summary Judgment of Non-Infringement of the Asserted Claims of the '7286, '3286, and '473 Patents-in-Suit.)

2. Cordis Improperly Relies On Extrinsic Evidence To Alter The Patents' Explicit Definition Of "Biocompatible"

Cordis improperly relies on the extrinsic declaration of its expert, Dr. Mikos, to argue that [redacted] extrinsic evidence and cannot be used to change the crystal-clear definition set forth in the patents. *Phillips*, 415 F.3d at 1318-19.

Even if Dr. Mikos's declaration were considered, however, it would not justify overriding the explicit definition in the patents. [redacted]

[redacted]

The patent contains no such acknowledgement and, in fact, explicitly states the opposite. (Ex. 1, '7286 Patent, 6:37-39; 3:56-58 (JA-16-17).) [redacted] but this is not grounds for ignoring the patents' clear definitional language. Rather, it is more likely grounds for invalidating the patents under Section 112.[9]

Further, in declarations to the Patent Office attempting to overcome the Examiner's rejection of the claims of the 1997 Patents as obvious, Dr. Mikos highlighted the importance of biocompatibility in intravascular devices, since artery interiors apparently are particularly susceptible to negative tissue reaction. (*See* 4/22/09 Declaration of Antonios G. Mikos, Ph.D., submitted in connection with Reex. Cont. No. 95/001,096 ("4/22 Mikos Reex. Dec.") at ¶¶ 49, 50, 53 (Ex. B at BSC-A-32-33).) [redacted] supports the conclusion that, for purposes of the 1997 Patents, in order to be

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[8] Several of the opinions set forth in ¶ 55 of Dr. Mikos's declaration were not even part of the hundreds of pages of expert reports Cordis served during expert discovery. [redacted] was never mentioned in or attached to any of Dr. Mikos's previous reports. This provides an additional ground for disregarding these declarations.

[redacted]

considered "biocompatible," the polymers must not elicit ***any*** negative tissue reaction or mural thrombus formation.

Similarly, the various dictionary definitions of "biocompatible" that Cordis cites are extrinsic evidence and cannot be used to change the definition expressly set forth in the patents. *Phillips*, 415 F.3d at 1322 ("There is no guarantee that a term is used in the same way in a treatise [or dictionary] as it would be by the patentee"); *Nystrom v. TREX Co.*, 424 F.3d 1136, 1145 (Fed. Cir. 2005) ("in the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to the public – i.e., those of ordinary skill in the art – that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source"); *Free Motion Fitness, Inc. v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1348 (Fed. Cir. 2005) (dictionary definitions may also be consulted in order to arrive at the ordinary and customary definition, so long as those definitions are not contradicted by the intrinsic evidence).

In any event, the most common dictionary definition of "biocompatible" appears to be not "causing toxic or injurious effects" and "not causing immunological response." [redacted] [redacted] These definitions are more supportive of BSC's construction than Cordis's.

3. The Patents' Definition Of Biocompatible Is Clear And Concise

While Cordis complains that the definition of "biocompatible" set forth in the patents would be "potentially confusing" to the jury (Cordis Brief at 17), it is transparent that the stark clarity of BSC's (and the patents') definition is what troubles Cordis. Nothing could be clearer than the definition provided in the patents: if a polymer elicits any negative tissue reaction or mural thrombus formation, then it is not biocompatible. Cordis's problem is not that BSC's and

the patents' definition is actually "confusing," but rather that it compels summary judgment of non-infringement. (*See* Plaintiffs' Opening Brief in Support of Their Motion for Summary Judgment of Non-Infringement of the Asserted Claims of the '7286, '3286, and '473 Patents-in-Suit (D.I. 260) at 3, 17-19; *see also* BSC's Opening Brief in Support of Its Motion for Summary Judgment of Non-Infringement of the Asserted Claims of the '662 Patent-in-Suit (D.I. 262 from C.A. 07-CV-765) at 2, 15-17.) Cordis's argument in this regard is particularly specious, since Cordis's proposed definition itself is facially indefinite. (BSC Opening Brief at 13.) Even if it were confusing (which it is not), the Court still must adopt the definition explicitly propounded by the inventors in their patents.

C. "Polymer," "Copolymer," And Related Terms

Cordis would like to ignore the plain language of its own claims and the inevitable result of that plain language. No matter how they get twisted and turned, the claims are clear – polymers and copolymers are different. Although BSC acknowledges that the word "polymer" can, in some contexts, refer to both homopolymers (wherein all the monomers are the same) and copolymers (consisting of more than one type of monomer), where "polymer" is used in contradistinction to "copolymers" – as in the 1997 Patents – "polymer" refers specifically to homopolymers. [redacted]

[10] The Responsive Hopfenberg Rpt. is attached as Exhibit B to the Declaration of Harold B. Hopfenberg, Ph.D., which was filed concurrently with BSC's Answering Brief in Opposition to Johnson & Johnson and Cordis Corporation's Motion for Partial Summary Judgment of Infringement of Claim 9 of the '3286 Patent.

[redacted] The claims of the 1997 Patents expressly distinguish "polymer" from "copolymer" when, for example, they provide lists of polymeric materials such as "acrylate-based ***polymer or copolymer***, a fluorinated polymer, or a mixture thereof." (Ex. 1, '7286 Patent, 8:18-20 (JA-18) (emphasis added).) BSC has appropriately used the claim language itself as the most important indicator of which definition of "polymer" applies in the context of the claims.

Cordis submits much extrinsic evidence to suggest that the claim term includes both homopolymers and copolymers. Yet, for all of its hand-waving and extrinsic evidence, Cordis has no logical explanation for why "polymer" should include all copolymers when the word is used alone or is modified by "fluorinated" but not when the word is modified by "acrylate-based." [11]

Cordis's argument that the claim language actually supports its construction (Cordis Brief at 7-8) is flawed. For instance, Cordis cites to dependent claims 10, 17, 19, and 22 of the '3286 Patent as allegedly requiring that the "polymer" in the "polymer/drug mixture" of claim 1

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11 [redacted] There is no single word in the English language comparable to "fluorinated" to describe an acrylate-based compound. That is why "acrylate-based" had to be used. Neither modifier, though, changes the fundamental relationship between "polymers" and "copolymers." [redacted]

consists of various copolymers. However, none of the dependent claims recite "wherein the polymer of claim 1 is [a copolymer]."[12] Rather, they simply recite that the coating may also "comprise" various polymers or copolymers. These polymers or copolymers are therefore present ***in addition to*** the drug/polymer mixture recited in claim 1 and do not modify the meaning of the word "polymer" in that claim.[13] In short, claim 1 requires that the coating comprise a polymer/drug mixture and that the drug be rapamycin or a macrocyclic lactone analog thereof. Certain dependent claims require that the coating also comprise certain additional polymers or copolymers. This is consistent with a definition of "polymer" which excludes copolymers.

Likewise, contrary to Cordis's argument, claims 1 and 4 of the '473 patent support a definition of polymer that ***excludes*** copolymers. To begin with, claim 4 explicitly uses "polymer" to distinguish from "copolymer" when it recites "wherein said biocompatible polymeric carrier further comprises an acrylate based polymer or copolymer." (Ex. 3, '473 Patent at 8:31-33 (JA-57).) Further, claim 4 is not stating that the "at least one nonabsorbable polymer" that is present in the polymeric carrier as part of claim 1 can be "an acrylate based copolymer." Rather, the use of the word "comprises" means only that the polymeric carrier has both a nonabsorbable polymer (as recited in claim 1), and also has an acrylate-based polymer or copolymer (as recited in claim 4). This does not argue against BSC's definition of "polymer."

Finally, the prosecution history cited by Cordis does not change the conclusion compelled by the very claim language itself. Cordis simply notes that the Patent Office rejected

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[12] The inventors certainly knew how to use this formulation if they wanted to; in claim 1 there is a requirement that the "drug is rapamycin...." (Ex. 2, '3286 Patent at 7:52-53 (JA-38).)

[13] The use of the open-ended term "comprise" indicates an additional element that is present in the coating.

a claim including a "polymer mixed carrier" (a term not at issue here) by citing a patent that discloses both polymers and copolymers.[14] (Cordis Brief at 8-9.) This says nothing about whether "polymer" as used in the 1997 Patents' claims includes or excludes copolymers; the prior art patent in question would have invalidated the then-pending claim under either definition. This serves merely as an example of one prior art patent (extrinsic evidence) in which the word "polymer" was used in a broad sense to include copolymers. It provides no insight as to the meaning of "polymer" as used in the claims at issue.

Cordis's protestations notwithstanding, BSC's proposed construction of "polymer" is entirely consistent with the intrinsic evidence. "Polymer" is a term that has multiple ordinary meanings and BSC has chosen the meaning that is dictated by the claim language itself – the most important intrinsic evidence available. *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1304 (Fed. Cir. 2001); *Interactive Gift Express, Inc. v. CompuServe, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001).

D. Stent Having a "Coating" "Applied Thereto" And Related Terms

Many of the claims of the 1997 Patents are directed to a stent having a "coating" "applied thereto" wherein the coating comprises a drug in a polymeric carrier. These terms are discussed below.

1. "Coating"

The intrinsic evidence is clear. The specification describes the coating as being a single "thin" layer that is applied directly to the stent surface:

[redacted]

> The conventional approach has been to incorporate the therapeutic agent into a polymer material which is then coated on the stent. The ideal coating material must be able to adhere strongly to the metal stent both before and after expansion....and be as thin as possible so as to minimize the increase in profile.
>
> ***
>
> Polymer/drug mixture is applied to the surfaces of the stent by either dip-coating, or spray coating, or brush coating or dip/spin coating or combinations thereof,...

(Ex. 1, '7286 Patent at 3:47-60, 3:61-4:2; 4:63-5:7; 6:47-52 (JA-16-17) (emphasis added).)

Cordis must admit that no intrinsic evidence supports its construction of coating to mean multiple ***layers***. Further, the plain language of the claims refers to the coating layer as a singular layer. (*See, e.g.*, Ex. 2, '3286 Patent at claim 1 (JA-38); Ex. 3, '473 Patent at claim 1 (JA-57).) In the face of this intrinsic evidence, as well as the ordinary meaning of "coating" (BSC Opening Brief at 24), Cordis's resort to the extrinsic Mikos Dec. to support its proposed construction is unavailing. *Phillips*, 415 F.3d at 1318; *DESA IP*, 211 Fed. Appx. at 938; *Network Commerce*, 422 F.3d at 1361.

[redacted] The fact that other patents, such as Ding, describe stents with multiple coatings does not change the fact that Cordis's inventors chose neither to claim nor describe multiple-layer coatings as part of their invention in the 1997 Patents. Moreover, in submissions to the Patent Office, ***Cordis and Dr. Mikos expressly distinguished the Ding patent from the 1997 Patents on the ground that Ding had multiple layers***. (BSC Opening Brief at 25-26.) This type of cynical behavior – telling one thing to the Patent Office to distinguish prior art and the opposite to the Court during a *Markman* proceeding – is precisely why courts should not rely on extrinsic evidence to vary the meaning of claims.

2. "Applied Thereto" "Is Applied" To The Stent

BSC proposes that "applied thereto" be construed to mean "brought into direct contact with the stent surface," giving meaning to the word "thereto," which Cordis would effectively remove from the claim. Cordis admits that "thereto" means "to that." (Cordis Brief at 19.) BSC's proposed construction simply identifies the "that" to which the coating is applied – namely the metallic surface of the stent. In short, BSC is applying the ordinary meaning of the claim language.

BSC's construction is consistent with the remainder of the intrinsic evidence. As noted in BSC's Opening Brief, the specification expressly discusses the coating being applied directly to the stent surface. (*See, e.g.*, Ex. 1, '7286 Patent at 3:47-60; 6:50-54 (JA-16-17).) Cordis, in contrast, does not and cannot point to anything in the 1997 Patents referring to a primer coating between the coating and the stent. To the contrary, the patent teaches the opposite – that the coating should "be as thin as possible so as to minimize the increase in profile." (Ex. 1, '7286 patent, at 3:53-54 (JA-16).) Cordis's extrinsic evidence that one of ordinary skill in the art would have known that primer coatings could be used on stents does not change what the inventors actually described and claimed as their invention: a coating layer applied directly to the surface of the stent.

E. "An Amount Effective To Inhibit Neointimal Proliferation"

The specification of the 1997 Patents itself flatly contradicts Cordis's argument that the specification "clearly and unambiguously" uses "inhibit" to mean "reduce." Indeed, in its attempt to import functional limitations into the term "analog," Cordis emphasized the specification's statement that: "an agent which ***prevents*** inflammation and the proliferation of SMC combined with a stent may provide the most efficacious treatment for post-angioplasty restenosis." (Ex. 1, '7286 Patent at 5:66-6:2 (JA-17) (emphasis added).) Cordis then argued that

this passage mandated that the analogs of rapamycin "inhibit" inflammation and hyperproliferation. (Cordis Brief at 26.) Cordis's implicit admission that the specification uses "prevent" interchangeably with "inhibit" supports BSC's proposed construction of "inhibit: "an amount sufficient to stop neointimal proliferation." And, the mere fact that the construction required by the specification of the patents-in-suit may potentially limit the claims to a device that may be difficult to achieve is not dispositive. *See generally Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("[e]ven a nonsensical result does not require the court to redraft the claims"); *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999) ("Courts do not rewrite claims; instead, [they] give effect to the terms chosen by the patentee."). Indeed, in the patents-in-suit, the Cordis inventors admit that they were pursuing an ideal that they had not realized. (Ex. 1, '7286 patent, at 5:59-60 ("the ideal agent for restenosis has not yet been identified.") (JA-17).)

Cordis's assertion that the inventors "never suggested" that the claimed stents would stop neointimal proliferation is simply wrong. The passage quoted above expressly refers to "an agent that prevents inflammation and the proliferation of SMC." The specification similarly describes the intended use of the claimed stents: "Uses: for inhibition of cell proliferation to ***prevent*** neointimal proliferation and restenosis." (Ex. 1, '7286 Patent at 6:26-28 (JA-17) (emphasis added).) This is far more than a mere "suggestion" that the claimed stents will stop proliferation and restenosis; it is an affirmative claim that they will.[15] [redacted] but these do not

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15 [redacted] the inventors claim in the 1997 Patents stents will prevent (*i.e.*, stop) neointimal proliferation and restenosis in humans.

change the intrinsic evidence, including the statements made by the inventors that the claimed stents would, in fact, stop proliferation and restenosis when used in ***humans***.

Further, the dictionaries cited by Cordis do not support its argument that the ordinary meaning of inhibit is to reduce. ***Every*** dictionary cited by Cordis (like the dictionary definition cited by BSC) defines "inhibit" to mean "prohibit." (*See* Appendix of Exhibits to Opening Markman Brief of Johnson & Johnson, Cordis and Wyeth Volume I of IV (D.I. 272) at Ex. 10.) Some of them include definitions such as "prevent" "restrain" and "check," which are synonyms for "stop." All of these definitions support BSC's proposed construction.

[redacted]

[redacted] When arguing to the Patent Office during the reexamination proceedings that the claimed invention of the 1997 Patents was not obvious, Dr. Rogers repeatedly asserted that the Cypher stent, which purportedly embodies the invention of the 1997 Patents, "solv[ed] the problem of restenosis." (Ex. V, 4/22/09 Declaration of Campbell Rogers, M.D., submitted in connection with Reex. Cont. No. 95/001,096 ("4/22/09 Rogers Reex. Dec.") at ¶¶ 10, 11, 13, 28, 94 (BSC-A-354-387).) Dr. Rogers further attributed Cypher's ability to have "solved" restenosis as the reason for its commercial success. (*Id.* at ¶ 28 (BSC-A-360-361).) He touts the Cypher stent's "remarkable clinical result of '***zero restenosis***'" (*id.* at Section IV.B (emphasis added); *see also* ¶ 42 (BSC-A-364)), describes clinical trials that purportedly "confirmed the success of the Cypher stent in ***preventing*** restenosis" (*id.* at ¶ 36 (BSC-A-362) (emphasis added)), quotes researcher's findings regarding the "virtual ***elimination*** of in-stent neointimal hyperplasia" (*id.* at ¶ 37 (BSC-A-362-363)) and criticizes the prior art for its inability to achieve the "prevention of restenosis." (*Id.* at ¶ 49 (BSC-A-368).) [redacted]

[redacted]

F. "Provides a Controlled Release ... Over a Period of Several Weeks"

Cordis complains that BSC's construction requires that all of the drug be discharged over a period of several weeks. However, BSC's construction does not require that all of the drug be discharged over the recited time period.

As explained in BSC's Opening Brief, however, Cordis's proposal remains indefinite.

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[16] If the Court were to adopt Cordis's proposed construction of "inhibit," it should preclude Cordis from offering at trial any evidence of the commercial success of Cypher to support a claim of non-obviousness. The performance of Cypher can be an indicator of non-obviousness, ***provided that its commercial success was the result of the claimed invention and not unclaimed features***. *See Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006). The success of Cypher, however, arises (according to Cordis) from the elimination of neointimal proliferation and restenosis, which far exceeds that which Cordis now argues is required by the claims.

II. CLAIM TERMS FROM THE '662 PATENT

A. Rapamycin And Its Analogs

1. "Rapamycin"

Cordis and BSC disagree on whether the Court should define rapamycin with reference to its chemical structure. For the same reasons set forth *supra* at pp. 3-4, the Court should adopt BSC's construction of "rapamycin," which contains a depiction of rapamycin's chemical structure.

Although Cordis complains that BSC's construction of this term does not expressly include "all" analogs, derivatives, congeners, etc. (Cordis Brief at 23), BSC's construction comes directly from a formal definition of this term in the specification: "Rapamycin as used throughout this application shall include rapamycin, rapamycin analogs, derivatives, and congeners that bind FKBP12 and possess the same pharmacologic properties as rapamycin." (Ex. 4, '662 Patent at 5:48-51 (JA-75).) In any event, it would not change the meaning of the construction if the Court were to add the word "all" to BSC's construction immediately before the word "analogs."

2. "Macrocyclic Triene Analog" Of Rapamycin

With respect to the claim term "macrocyclic triene analog" Cordis again improperly insists that the structure possess the exact same macrocyclic triene ring as rapamycin. For the reasons set forth in BSC's Opening Brief at 32, as well as *supra* at 7-9, there is no sound basis for construing the term in this manner.

Cordis also adds the functional limitation "which is capable of inhibiting both the inflammatory response known to occur after arterial injury and stent implantation, as well as the smooth muscle cell hyperproliferative response," again relying on the extrinsic testimony of Dr. Sabatini. The addition of this language – which does not appear anywhere in the '662 patent –

would be entirely arbitrary. As was the case with respect to "macrocyclic lactone analog," Cordis has no good explanation why this particular language should be added, as opposed, for instance, to a requirement that the analog have the same pharmacologic properties as rapamycin

BSC submits that the claimed "macrocyclic triene analogs" should have the additional functional requirement of binding to FKBP12 and possessing the same pharmacologic properties as rapamycin.[17] Unlike the 1997 Patents, in discussing analogs, the '662 Patent repeatedly states that they "bind FKBP12 and possess the same pharmacologic properties as rapamycin." (*See* Ex. 4, '662 Patent at 5:48-51 (JA-75); 7:29-32 (JA-76); 11:38-42 (JA-78).) Thus, BSC's proposed construction finds a sound basis in the patent specification, unlike the additional language proposed by Cordis.[18]

B. "Biocompatible"

Cordis appears to argue that the Court should use Cordis's definition of "biocompatible" for the '662 patent, even if the Court adopts BSC's definition for the 1997 Patents. (Cordis Brief at 17.) Given the overlap of subject matter, disclosures, and inventors, the Court should apply

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[17] BSC's proposed construction of "macrocyclic triene analog" refers back to its previous definition of rapamycin and thus includes the requirement that any "analogs, derivatives, [or] congeners" of rapamycin, including any "macrocyclic triene analog," "bind FKBP12 and possess the same pharmacologic properties as rapamycin."

[18] Cordis appears to oppose any requirement that the analog have the same pharmacologic properties as rapamycin, even though this language is firmly grounded in the specification, unlike the arbitrary language Cordis seeks to add. Should the Court nevertheless rule that the portions of the '662 patent cited above do not mandate that a "macrocyclic triene analog" "bind FKBP12 and possess the same pharmacologic properties as rapamycin," then BSC submits that the Court should decline to add any functional limitation to this claim term and simply hold that it means "a macrocyclic triene molecule with a structure similar to rapamycin."

the same definition for both patents.[19] *See AutoMed Techs., Inc. v. Microfil, LLC*, 244 Fed. Appx. 354, 357 (Fed. Cir. 2007).

Even if the Court declines to adopt BSC's construction of "biocompatible" for the '662 patent, it should not apply Cordis's. As noted above, Cordis's construction does not fairly represent the ordinary meaning of the term and also is facially indefinite. Rather, if the Court is inclined to consider the various dictionary definitions of "biocompatible," it should find that the ordinary meaning of "biocompatible" is "does not cause toxic or injurious effects or immunological response." [redacted]

C. "Affixed to the Intraluminal Stent"

Cordis argues that "affixed to the stent" does not require the coating to be actually affixed to the stent but merely affixed to something else, namely a primer coating that is affixed to the stent. As with the "applied thereto" limitation discussed above, it is Cordis – not BSC – that is diverging from the ordinary meaning of the claim language. The specification discloses what is meant by affixing the drug carrier to the stent: it is applied to the stent surface. (Ex. 4, '662 Patent at 16:22-25 (JA-80).) There is no discussion of a primer coating whatsoever. Accordingly, BSC's construction better comports with the ordinary meaning of the claim language and the '662 Patent specification.

D. "In-Stent Late Loss" and Related Terms

As BSC explained in its opening brief – and Cordis does not really dispute – a particular protocol for measurements of lumen diameter are required by and part and parcel of quantitative coronary angiography ("QCA"). (BSC Opening Brief at 35-36.) Cordis's position – that ***any***

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[19] The word "biocompatible" appears only once in the '662 patent's specification. (Ex. 4, '662 Patent, 16:22-25 (JA-80).)

clinically acceptable protocol could be used to determine minimal lumen diameter as part of the calculation for in-stent late loss under the '662 Patent (Cordis Brief at 38) – would render the claims indefinite because the same stent could meet the requirement for in-stent late loss under one protocol, yet fail to meet it under a different protocol. (BSC Opening Brief at 35.) Without knowing the protocol for measuring the lumen diameters, one would be unable to determine whether one infringes. The claim construction should clarify to the fact finder the reality that in-stent late loss as measured by QCA requires a particular protocol.

E. "Human Population"

BSC's proposed construction of the term "human population" – "a class of people distinguished by particular traits or characteristics" – incorporates the ordinary meaning of the term. (BSC Opening Brief at 36). In contrast, Cordis never suggests that its proposed construction – which includes only candidates for coronary stent therapy who "would be a suitable group for testing in a clinical trial for stents" (Cordis Brief at 32) – reflects the ordinary meaning of this claim term. In fact, Cordis's proposed construction represents a change from its initial definition of "human population," which was simply "a group of human beings." Cordis likely changed its position because it does not know the mean in-stent late loss for the entire group of people who have received any particular PROMUS stent and, thus, has no way to prove infringement under its original claim construction.

Cordis's argument that the intrinsic evidence supports its new, unorthodox construction of "human population" overlooks the fact that the '662 Patent specification nowhere uses the term "population," much less defines it. Cordis therefore ironically relies almost exclusively on extrinsic evidence to support its argument that the intrinsic evidence requires the additional limitations it writes into the claim. Extrinsic evidence cannot, however, be used to alter the

ordinary meaning of a claim term in this fashion. *Phillips*, 415 F.3d at 1322; *see Vitronics,* 90 F.3d at 1583.

In any event, the extrinsic evidence cited by Cordis fails to support its claim construction. While Cordis notes that the mean in-stent late loss data reported in Table 5 of the patent came from a clinical trial, this unremarkable premise does not lead to the conclusion that "human population" means only people who "would be a suitable group" for testing in such a trial. The inventors did not even bother to describe the inclusion or exclusion criteria for the clinical trial that presumably gave rise to the data in Table 5 of the patent; thus, the intrinsic evidence would not even support a claim construction that was limited to the particular population used in the clinical trial reported in Table 5. Nor does the '662 Patent list any criteria that would make a patient suitable for clinical trials, even assuming that such a list could be generated. If suitability for a clinical trial were the hallmark of the definition of "human population" as Cordis now asserts, the patent would have made some mention of this suitability, and what it means in practice.

In addition to the lack of any intrinsic evidence to support it, Cordis's proposed construction of the term "human population" must be rejected because it would render Cordis's claims fatally indefinite. Indeed, Cordis's attempt to limit the population in which the claimed stent must achieve the claimed in-stent late loss to those eligible for clinical trials raises many more questions about the scope of the various claims in the '662 Patent than it answers. For example:

- Is it Cordis's position that the claims are limited only to those stents that are implanted in a clinical trial setting (in which case, the overwhelming majority of the accused PROMUS stents would not infringe)?
- Which clinical trials are being referenced, and which patients are suitable for them?

- Do the claims cover stents that can achieve the claimed mean in-stent late loss in some groups of people but not others? If so, then will a stent infringe only when implanted into one type of patient but not another?

Because these questions are not answered clearly by the patent, Cordis's proposed construction would render the claims indefinite, since a stent manufacturer must be able to determine the scope of the claims to avoid infringement. *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993) ("Since the evidence shows that the claims at issue here are not sufficiently precise to permit a potential competitor to determine whether or not he is infringing, we also agree with the district court's determination that the claims are invalid for failure to satisfy the 'definiteness' requirement of *section 112*, second paragraph"); *Howmedica Osteonics Corp. v. Tranquil Prospects, Ltd.* 401 F.3d 1367, 1371 (Fed. Cir. 2005).

CONCLUSION

For the foregoing reasons and those set forth in its Opening Brief, BSC respectfully requests that the Court adopt BSC's proposed claim constructions.

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CERTIFICATE OF SERVICE

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